CLAIMS

What is claimed is:

1. A hydrophilic colloidal dispersion, comprising:

a water-insoluble or water soluble active compound; and

an amphiphilic polymer which wraps said active compound in a non-crystalline manner to form a nano-sized molecular entity in which no valent bonds are formed,

wherein said amphiphilic polymer renders said molecular entity hydrophilic in water and bioavailable in the human body.

2. The hydrophilic colloidal dispersion as recited in claim 1, wherein said active compound is wrapped within said amphiphilic polymer via non-valent interactions between said polymer and said active compound such that said interactions fixate said active compound within said polymer to reduce molecular flexibility.

3. The hydrophilic colloidal dispersion as recited in claim 2, wherein said non-valent interactions include electrostatic forces, Van der Waals forces and hydrogen bonds.

4. The hydrophilic colloidal dispersion as recited in claim 2, wherein said active compound wrapped within said amphiphilic polymer does not form rigid matrices nor cross-linked polymers.

5. The hydrophilic colloidal dispersion as recited in claim 1, wherein said active compound wrapped in said amphiphilic polymer is fixated within said polymer.

6. The hydrophilic colloidal dispersion as recited in claim 1, wherein said nano-sized molecular entity is substantially spherical.

7. The hydrophilic colloidal dispersion as recited in claim 1, wherein said molecular entity having an active compound wrapped in said polymer exhibits reduced flexibility of said active compound and reduction of crystallinity.

8. The hydrophilic colloidal dispersion as recited in claim 1, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

9. The hydrophilic colloidal dispersion as recited in claim 1, wherein said active compound may comprise organic materials selected from the group consisting of pharmaceutical compounds, food additives, cosmetics, agricultural products and pet foods and other chemical compounds and/or intermediates.

10. The hydrophilic nano-sized soluble particles as recited in claim 3, wherein said active compound is selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones and other chemical compounds.

11. The hydrophilic nano-sized soluble particles as recited in claim 1, wherein said active compound is a pharmaceutical compound.

12. The hydrophilic colloidal dispersion as recited in claim 11, wherein said pharmaceutical compound may include chemotherapeutic agents, antibiotic agents and neoplastic agents.

13. The hydrophilic colloidal dispersion as recited in claim 12, wherein said antibiotic and neoplastic agents include erythromycin and clarithromycin.

14. The hydrophilic colloidal dispersion as recited in claim 1, wherein said amphiphilic polymer and said active compound form a polymer complex having a hydrophilic-lipophilic balance that renders said polymer complex soluble in water.

15. The hydrophilic colloidal dispersion as recited in claim 1, wherein said nano-sized molecular entity is in the range of from approximately 10 to approximately 1000 nanometers in size.

16. The hydrophilic colloidal dispersion as recited in claim 15, wherein said active compound in said molecular entity is in the range of approximately 1 to approximately 5 microns in size.

17. The hydrophilic colloidal dispersion as recited in claim 1, wherein said molecular entity is an inclusion complex.

18. The hydrophilic colloidal dispersion as recited in claim 1, wherein said active compound of the molecular entity exists in an amorphous, non-crystalline form.

19. The hydrophilic colloidal dispersion as recited in claim 1, wherein said active compound is lipophilic.

20. A method for forming an inclusion complex comprising hydrophilic nano-sized soluble particles, the method comprising the steps of:

(a) preparing a polymer solvent comprising amphiphilic polymer molecules in an aqueous solvent;

(b) preparing a carrier solvent comprising lipophilic compounds in a non-aqueous solution;

(c) adding said carrier solution to said polymer solution to form an emulsion;

(d) dispersing said lipophilic compounds in said emulsion by adding said emulsion to a turbulent zone in said polymer solution wherein said lipophilic compounds form nano-sized lipophil compounds in a nano-emulsion;

(e) removing said carrier solvent from said nano-emulsion, wherein said polymer molecules surround said nano-sized lipophil compounds to form said hydrophilic inclusion complex.

21. The method as recited in claim 20, wherein said polymer solution in said preparing step (a) is contained in a first vessel of a chemical reactor and said lipophil solution is contained in a second vessel of a chemical reactor.

22. The method as recited in claim 21, wherein said dispersing step (d) occurs within a turbulent flow in the polymer solution within said chemical reactor.

23. The method as recited in claim 22, wherein said turbulent flow is generated by a high sheer apparatus.

24. The method as recited in claim 20, wherein said lipophil solution is comprised of lipophilic compounds selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones and other chemical compounds and/or intermediates.

25. The method as recited in claim 20, wherein said lipophilic compounds are insoluble in water.

26. The method as recited in claim 20, wherein said polymer is an amphiphilic polymer.

27. The method as recited in claim 20, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

28. The method as recited in claim 20, wherein said removing step further comprises the step of evaporating said carrier solvent via a drying technique.

29. The method as recited in claim 28, wherein said drying technique is vacuum distillation.

30. The method as recited in claim 28, wherein said drying technique is lyophilization.

31. The method as recited in claim 20, wherein said emulsion in said adding step (c) has a Reynolds number of not less than 10,000.

32. The method as recited in claim 20, further comprising the step of heating said mixture of polymer solution with said carrier to generate steam which condenses and dissolves said lipophilic compounds to form said lipophilic solution.

33. The method as recited in claim 30, wherein said polymer solution is heated to a temperature above the boiling point of the carrier solution but lower than the boiling point of the polymer solution.

34. A chemical reactor for forming an emulsion used in the preparation of an inclusion complex, comprising:

a first vessel for a containing a polymer solution;

a second vessel for containing lipophilic compounds and non-aqueous solvent of lipophilic compounds;

a carbon dioxide balloon for providing carbon dioxide to the solvent in said second vessel; and

a dispersing apparatus for dispersing said solution of lipophilic compounds in a carrier within said polymer solution, said dispersing apparatus being positioned within said first vessel and which creates a high sheer and turbulent flow within said polymer solution, said first and second vessels being connected to each other to permit continuous circulation of the carrier and wherein said lipophil migrates from said second vessel to said first vessel.

35. The chemical reactor as recited in claim 34, wherein said dispersing apparatus disperses said lipophilic compounds in said lipophilic solution into nano-sized particles.

36. The chemical reactor as recited in claim 35, wherein said dispersing apparatus is a nano-disperser.

37. The chemical reactor as recited in claim 34, wherein said dispersing apparatus operates in said first vessel at a rate of approximately 5,000-30,000 revolutions per minute.

38. The chemical reactor as recited in claim 34, further comprising a first heating apparatus for heating said polymer solution in said first vessel.

39. The chemical reactor as recited in claim 34, further comprising a mixing apparatus positioned below said second vessel for mixing said lipophilic solution in said second vessel.

40. The chemical reactor as recited in claim 34, further comprising a first condenser connected to a vacuum pump, said vacuum pump extending into said first vessel.

41. The chemical reactor as recited in claim 34, further comprising a second condenser connected to said second vessel.

42. The chemical reactor as recited in claim 34, wherein said polymer solution in said first vessel is in fluid communication with said lipophilic solution in said second vessel via a tube connected between said first vessel and said second vessel.

43. The chemical reactor as recited in claim 42, wherein said lipophilic solution is added to said polymer solution in said first vessel via said tube connected between said first vessel and said second vessel, said tube having an exit end extending within said polymer solution in said first vessel, wherein said lipophil solution which flows through said exit end of said tube enters said first vessel in said region of vigorous turbulent flow.

44. The chemical reactor as recited in claim 43, wherein said first vessel comprises an air space above said polymer solution.

45. The chemical reactor as recited in claim 44, wherein said first vessel further comprises a screen positioned therein above said polymer solution to prevent said turbulent flow from entering said air space above said polymer solution.

46. The chemical reactor as recited in claim 34, further comprising a pump for circulating said lipophil solution and said polymer solution between said first vessel and said second vessel.

47. A process for forming nano-sized soluble particles, comprising an active lipophilic or hydrophilic core wrapped in a non-crystalline manner within an amphiphilic polymer wherein no valent bonds are formed, the process comprising the steps of:

(a) preparing an emulsion or suspension comprising solution of amphiphilic polymer molecules in an aqueous solvent and a solution of active compound in a non-aqueous solvent carrier;

(b) dispersing said active compound within said emulsion or suspension, wherein said active compound forms nano-sized particles, said nano-sized particles forming a colloidal nano-dispersion; and

(c) removing said carrier solvent from said nano-dispersion, wherein said polymer molecules surround said lipophilic particles to provide said nano-sized soluble particles.

48. The process as recited in claim 47, wherein prior to the dispersing step (b), the process further comprises the step of heating the emulsion to a temperature lower than the boiling point of the emulsion, and above the boiling point of the carrier solvent.

49. The process as recited in claim 47, wherein said preparing, dispersing and removing steps occur in a chemical reactor.

50. The process are recited in claim 49, wherein said dispersing step (b) occurs within a turbulent high sheer flow in the polymer solution within said chemical reactor.

51. The process as recited in claim 47, wherein said lipophilic compound is selected from the group consisting of: organic materials selected from the group consisting of drugs, food additives, cosmetics, agricultural products and pet foods, and other chemical compounds and/or intermediates.

52. The process as recited in claim 47, wherein the polymer in said polymer solution is selected from the group consisting of: natural polysaccharides, polyacrylic acid

and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

53. The process as recited in claim 47, wherein prior to the preparing step (a), the process comprises the step of determining and calculating the characteristics and properties of said polymer molecule and said lipophilic compound to be used in the formation of said nano-sized soluble particles.

54. The process as recited in claim 52, wherein said polymer is selected based upon the molecular weight, dimensions, polarity and solubility in non-aqueous solvents of the lipophilic compound to be used in the formation of said nano-sized soluble particles.

55. The process as recited in claim 47, wherein said polymer is selected via an algorithm which considers one or more of the following characteristics of the polymer: molecular weight, basic polymer chain length, length of kinetic unit, solubility in water, degree of solubility, degree of polymeric chain flexibility, integral hydrophilic-lipophilic balance, and polarity of hydrophilic groups.

56. The process as recited in claim 50, wherein said emulsion which enters the turbulent high shear flow in said dispersing step (b) has a Reynolds number of not less than 10,000.

57. The process as recited in claim ~~47, wh~~erein said nano-sized soluble particles exist as an amorphous, non-crystalline form.

58. A method for forming a hydrophilic inclusion complex in a chemical reactor, the method comprising the steps of:

(a) preparing a dispersion in a first vessel of said chemical reactor, said dispersion comprising a carrier solvent and an amphiphilic polymer solution;

(b) adding an active compound to a second vessel of said chemical reactor;

(c) heating said dispersion wherein vapor from said dispersion condenses in said second vessel and dissolves said active compound to form an active compound solution;

(d) adding said active compound solution to said dispersion in said first vessel, said active compound solution being added to said first vessel in the vicinity of a disperser apparatus positioned in said first vessel;

(e) dispersing said active compound solution wherein said active compounds form nano-sized particles in a nano-emulsion or suspension;

(f) removing said carrier solvent from said nano-emulsion or nano-suspension wherein said amphiphilic polymer surrounds said nano-sized particles to provide said hydrophilic inclusion complex having an amorphous, non-crystalline form.

59. The method as recited in claim 58, wherein said dispersing step (e) occurs within a turbulent flow in the polymer solution within said first vessel.

60. The method as recited in claim 58, wherein said lipophil solution is comprised of lipophilic compounds selected from the group consisting of: peptides and polypeptides, nucleotides and co-ferments, vitamins, steroids, porphyrins, metal-complexes, purines, pyrimidines, antibiotics and hormones, and other chemical compounds and/or intermediates.

61. The method as recited in claim 58, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

62. The method as recited in claim 58, wherein said removing step (f) further comprises the step of evaporating said carrier solvent via a drying technique.

63. The method as recited in claim 62, wherein said drying technique is vacuum distillation.

64. The method as recited in claim ~~62,~~ wherein said drying technique is lyophilization.

65. The method as recited in claim 58, wherein said emulsion added to said polymer solution in said adding step has a Reynolds number of not less than 10,000.

66. The method as recited in claim 58, wherein said polymer solution is heated to a temperature above the boiling point of the carrier solvent but lower than the boiling point of the polymer solution.

67. Nano-sized soluble particles comprising an active lipophilic or hydrophilic core wrapped in a non-crystalline manner within an amphiphilic polymer in which no valent bonds are formed.

68. The nano-sized particles as recited in claim 67, wherein said core is wrapped within said amphiphilic polymer via valent interactions between said polymer and said core such that said interactions fixate said core within said polymer to reduce molecular flexibility.

69. The nano-sized particles as recited in claim 68, wherein said valent interactions include electrostatic forces, Van der Waals forces and hydrogen bonds.

70. The nano-sized particles as recited in claim 67, wherein said active core wrapped in said amphiphilic polymer does not form rigid matrices nor cross-linked polymers.

71. The nano-sized particles as recited in claim 67, wherein said active core wrapped in said amphiphilic polymer is fixated within said polymer.

72. The nano-sized particles as recited in claim 67, wherein said particles are substantially spherical.

73. The nano-sized particles as recited in claim 67, wherein said active core is an amorphous non-crystalline entity.

74. The nano-sized particles as recited in claim 67, wherein said particles having a core wrapped in said polymer exhibits reduced flexibility of said core and reduction of crystallinity.

75. The nano-sized particles as recited in claim 67, wherein said active core and said polymer are dissolved in two different and immiscible liquids and said particles are produced by gradual addition of a solution of said core solution to said polymer solution under vigorous stirring.

76. The nano-sized particles as recited in claim 67, wherein said amphiphilic polymer is selected from the group consisting of: natural polysaccharides, polyacrylic acid and its derivatives, polyethylene imine and its derivatives, polymethacrylic acid and its derivatives, polyethylene oxide and its derivatives, polyvinyl alcohol and its derivatives, polyacetylene derivatives, polyisoprene derivatives and polybutadiene derivatives.

77. The nano-sized particles as recited in claim 67, wherein said active core is a pharmaceutical compound.

78. The nano-sized particles as recited in claim 77, wherein said pharmaceutical compound may include chemotherapeutic agents, antibiotic agents and neoplastic agents.

79. The nano-sized particles as recited in claim 78, wherein said active core is erythromycin or clarithromycin.

80. The nano-sized particles as recited in claim 67, wherein said particles are in the range of from approximately 10 to approximately 1000 nanometers in size.

81. A chemical reactor for forming an emulsion used in the preparation of hydrophilic nano-sized soluble particles, comprising:

a first vessel for a containing a polymer solution;

a second vessel for containing lipophilic compounds and non-aqueous solvent of lipophilic compounds;

a carbon dioxide balloon for providing carbon dioxide to the solvent in said second vessel; and

a dispersing apparatus for dispersing said solution of lipophilic compounds in a carrier within said polymer solution, said dispersing apparatus being positioned within said first vessel and which creates a vigorous high shear and turbulent flow within said polymer solution, said first and second vessels being connected to each other to permit continuous circulation of the carrier and wherein said lipophil migrates from said second vessel to said first vessel.

82. The chemical reactor as recited in claim 81, wherein said dispersing apparatus disperses said lipophilic compounds in said lipophilic solution into nano-sized particles.

83. The chemical reactor as recited in claim 82, wherein said dispersing apparatus is a nano-disperser.

84. The chemical reactor as recited in claim 81, wherein said dispersing apparatus operates in said first vessel at a rate of approximately 5,000-30,000 revolutions per minute.

85. The chemical reactor as recited in claim 81, further comprising a first heating apparatus for heating said polymer solution in said first vessel.

86. The chemical reactor as recited in claim 81, further comprising a mixing apparatus positioned below said second vessel for mixing said lipophilic solution in said second vessel.

87. The chemical reactor as recited in claim 81, further comprising a first condenser connected to a vacuum pump, said vacuum pump extending into said first vessel.

88. The chemical reactor as recited in claim 81, further comprising a second condenser connected to second vessel.

89. The chemical reactor as recited in claim 81, wherein said polymer solution in said first vessel is in fluid communication with said lipophilic solution in said second vessel via a tube connected between said first vessel and said second vessel.

90. The chemical reactor as recited in claim 89, wherein said lipophilic solution is added to said polymer solution in said first vessel via said tube connected between said first vessel and said second vessel, said tube having an exit end extending within said polymer solution in said first vessel, wherein said lipophil solution which flows through said exit end of said tube enters said first vessel in said region of vigorous turbulent flow.

91. The chemical reactor as recited in claim 90, wherein said first vessel comprises an air space above said polymer solution.

92. The chemical reactor as recited in claim 91, wherein said first vessel further comprises a screen positioned therein above said polymer solution to prevent said turbulent flow from entering said air space above said polymer solution.

93. The chemical reactor as recited in claim 81, further comprising a pump for circulating said lipophil solution and said polymer solution between said first vessel and said second vessel.